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October 28, 2009

Margaret Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg:

I am writing in regards to the recent changes to the Vibrio vulnificus policy by the Food and Drug Administration. I am requesting that the FDA continue to work with the Interstate Shellfish Sanitation Conference towards their original goal of a 60% *Vibrio vulnificus* illness reduction plan.

On October 17, 2009 the Food and Drug Administration (FDA) advised the Interstate Shellfish Sanitation Conference (ISSC) that it intends to unilaterally change the seafood regulations regarding *Vibrio vulnificus* (*V.v.*). This new regulation being imposed by the FDA would prevent raw oysters from being served in the United States. The Oyster industry would be forced to implement this Post Harvesting Process, which is similar to pasteurization, using mild heat, freezing temperatures, high pressure and low-dose gamma radiation.

The Gulf Coast Oyster industry provides two-thirds of the nation's oysters and is a $500 million industry. The Oyster industry is already one the most regulated food industries in the United States. On average, the V.v infection rate from the consumption of raw Gulf Coast oysters is .00005%. The ISSC in conjunction with the FDA and its members work very hard to continue to reduce *V.v* from raw oysters.

The FDA had worked with the ISSC and the Gulf states over the past several years to formulate a 60% *V.v.* illness reduction plan. This *V.v.* illness risk reduction plan required Gulf oyster harvesters and dealers to invest substantial financial resources in on-board refrigeration systems. In many cases, dealers, decided to upgrade or replace their existing refrigeration systems. In the development of this plan, the FDA provided the Gulf States with a *Vibrio vulnificus* Risk Calculator. This FDA calculator is a useful tool allowing state shellfish regulators and industry to determine the best way for their state to meet the illness reduction goals of the ISSC.

Many of the Gulf State's shellfish regulatory agencies and oyster industry members have already begun the process enabling them to further reduce *V.v.* illnesses. The Mississippi Commission on Marine Resources recently completed the administrative process adopting changes to two of its oyster harvesting and handling regulations. This was done in order to

comply with the requirements of the *V.v.* risk reduction plan. The ISSC fully expected the FDA to support this process in accordance with the agreements they had made with the ISSC. Instead the FDA has proposed this unilateral action banning raw oysters, contrary to their agreement with the ISSC. The FDA is now requiring a Post Harvesting Process and abandoning their commitment to the ISSC and the Gulf oyster harvesters and industry. This decision is not consistent with the work that has been done by the FDA and the ISSC fighting V.v, and it does not make sense for the FDA to take on this new commitment.

From recent reports it is clear that the FDA is struggling to handle the responsibilities it already has. The FDA is understaffed to the point that the agency would need at least 27 years to inspect every foreign medical device plant that exports to the United States, according to a study done by the Government Accountability Office. Computer systems at the FDA are unable to accurately keep track of the number of overseas factories exporting products to the United States, and there is no consistent record of if or when inspections were done at these plants.

On average, according to the Government Accountability Office, foreign medical factories that bring products to the U.S. are inspected at a rate of once every 13 years, according to agency's records from 2002 to 2007. The growing number of Chinese factories sending prescription drugs and medical products to the U.S. are inspected at a rate of 2% per year. This means that it would take up to 50 years to inspect all of the Chinese facilities.

If the FDA is looking for new responsibilities to undertake, I would be more than willing to sit down and discuss the issue of foreign shrimp being illegally dumped into our markets from China. Foreign shrimp are grown in ponds that are completely unregulated and have absolutely no inspection process. They are filled with bacteria, hormones, and other substances that the FDA has not had the time to inspect. I would much rather see the FDA spend its time investigating foreign shrimp being exported to the United States than create new requirements on an industry that is already heavily regulated by the both the federal government and the states.

Thank you for your consideration in this matter. I look forward to hearing back from you about my request for the FDA to continue to work with the Interstate Shellfish Sanitation Conference towards their original goal of a 60% *Vibrio vulnificus* illness reduction plan.

Sincerely,

GENE TAYLOR
Member of Congress

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